IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	Sze et al.	Attorney Docket No:	UNIV0162
Serial No:	10/729,364	Group Art Unit:	3715
Filed:	December 5, 2003	Examiner:	Utama, Robert J.

Title: ULTRASOUND SIMULATOR FOR CRANIOSYNOSTOSIS SCREENING

APPEAL BRIEF

Bellevue, Washington 98004

March 30, 2009

TO THE DIRECTOR OF THE PATENT AND TRADEMARK OFFICE:

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

STATEMENT OF THE REAL PARTY IN INTEREST

The real party in interest in this appeal is hereby identified as the University of Washington, since all right and title in the invention and in the patent application on appeal has been assigned to the University of Washington, as evidenced by a chain of title from the inventors in the patent application identified above to the current assignee, as shown below.

1. An assignment of all rights and title in the present patent application was made by inventors **Raymond W. Sze** (assignment executed on February 10, 2004) and **Anh-Vu Ngo** (assignment executed on January 23, 2004) to the **University of Washington**. The assignments were recorded in the U.S. Patent and Trademark Office on March 22, 2004 at Reel 015124, Frame 0142 and on March 22, 2004 at Reel 015126, Frame 0538, respectively.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

STATEMENT OF RELATED CASES

No other prior or pending appeals, interferences, or judicial proceedings are known to any inventors, any attorneys or agents who prepared or prosecuted the application on appeal and any other person who was substantively involved in the preparation or prosecution of the application on appeal that are related to or will directly affect or be directly affected by or have a bearing on the Board's decision in this pending appeal.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

JURISDICTIONAL STATEMENT

The Board has jurisdiction under 35 U.S.C. § 134(a).

Examiner Robert Utama of Group Art Unit 3725 mailed a final rejection on October 28, 2008, setting a three-month shortened statutory period for response. The time for responding to the final rejection expired on January 28, 2009.

Appellants filed a timely Notice of Appeal on January 28, 2009.

Appellants filed this timely Appeal Brief on March 30, 2009.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

TABLE OF CONTENTS

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

TABLE OF AUTHORITIES

Statutes

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

STATUS OF AMENDMENTS

An amendment filed on January 28, 2009, after the final rejection, was entered by the Examiner.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

GROUNDS OF REJECTION TO BE REVIEWED

I. Rejection of Claims 1, 4, 5, 7-27 and 52-58 as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,708,836 (Gain et al. - hereinafter referred to as "Gain") in view of NPL#1, "Infant Skull Model and Sculpted Head" (Webb, Linda, retrieved on Jun 09, 2002, retrieved from internet <URL: **http://web.archive.org/web/20020609002343/http://www.lindawebb.com/infant_skull.htm**>, hereinafter referred to as "NPL#1") and further in view of U.S. Patent No. 2003/0208 (Cecchi, hereinafter referred to as "Cecchi").

II. Rejection of Claims 14-17, 21-26 and 52-58 as being unpatentable under 35 U.S.C. § 103(a) over Gain in view of NPL#1, in view of U.S. Patent No. 5,609,485 (Bergman et al., hereinafter referred to as "Bergman") and further in view of Cecchi.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

STATEMENT OF FACTS

1. In rejecting Claims 1-2, 4-27, and 52-58, the Examiner cites Gain in view of NPL#1 and further in view of Cecchi. Office Action dated 10/28/2008, p. 3.

2. In rejecting Claims 14-17, 21-26 and 52-58, the Examiner cites Gain in view of NPL#1 in view of Bergman and further in view of Cecchi. Office Action dated 10/28/2008, p. 9.

3. Gain is entitled "Process For Producing An Artificial Cranium And A Prosthetic Head." With respect to scope, Gain discloses that artificial craniums used for pedagogic purposes are satisfactory for the study of the anatomy, but that these craniums do not make it possible to carry out mechanical tests for shock resistance. Col. 1. ll. 33-43. Gain discloses a model having the same mechanical behavior and shape characteristics as a fresh cranium and a real head, respectively. Col. 1, ll. 61-65. With respect to content, Gain discloses that the artificial cranium must have the same shape and dimensions as a real human cranium. Col. 2, ll. 8-10. Gain discloses that the cavities corresponding to the natural cavities of a real human or animal cranium must have the same shape and dimensions. Col. 2, ll. 9-12. Gain discloses that the thickness of the material used must be adapted. Col 2, ll. 12-13. Gain discloses using different materials so that an equivalent resin thickness can be determined such that the compression strength at a given point of the artificial cranium is equal to the compression strength at the corresponding point on the fresh

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

cranium. Col. 5, ll. 42-60. Gain's FIG. 2 is entitled "A diagrammatic profile view of a human head." Col. 4, ll. 64-65. FIG. 2 includes a fracture that is not identified by a drawing element number. With respect to differences between the claims on appeal and the cited art, Gain's specification does not disclose either the term "suture" or the term "ultrasound." Gain's specification does not disclose how the different materials would appear in an ultrasound model. Gain does not disclose how its artificial cranium with its different materials would be relevant to ultrasound studies. Gain discloses structural analysis equations in col. 6 and col. 7. A person of ordinary skill in the art of Gain is someone with an engineering and testing background.

4. NPL#1 is entitled "Infant skull model and sculpted head." With respect to scope, NPL # 1 discloses the creation of life-like sculptures. See EVIDENCE SECTION, copy of http:lindawebb.com/aboutlinda.htm, and referred to in Office Action Response dated 6/8/07, p. 18, ll. 10-11. With respect to content, NPL#1 discloses a model of an infant skull on the right side of the picture. It discloses a sculpted head on the left side of the picture. NPL # 1 discloses that "Linda uses this skull model to help her achieve the proper head shape of an infant." See EVIDENCE SECTION, copy of http:lindawebb.com/infant_skull.htm, referred to in Office Action Response dated 6/8/07, p. 18, ll. 12-13. NPL # 1 discloses that the artist specializes in realistic, newborn sculptures. See EVIDENCE SECTION, copy of http:lindawebb.com/contents.htm, referred to in Office Action Response dated 6/8/07,

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

p. 18, line 14. One of ordinary skill in the art of NPL#1 would be an artisan who studies human anatomy in order to recreate life-like sculptures.

5. Cecchi is entitled "Embryo-Implanting Catheter Control System And Method Of The Same." With respect to scope, it discloses an improved catheter assembly, which is useful in performing embryo implants in a female's uterus. Paragraph. 0013. With respect to content, a portion of the catheter assembly can be tracked within the patient using ultrasound imaging equipment. Paragraph. 0048. Cecchi discloses varying the density of an echogenic portion in order to be seen or to be opaque, in images produced by ultrasonic imaging equipment. Paragraph. 0049.. With respect to differences between the claims on appeal and the cited art, Cecchi does not disclose either manipulating density of materials in a training simulator or how to manipulate the density of materials. Cecchi discloses a catheter assembly (Claim 1), a method for forming an echogenic end of an instrument (Claim 15) and a method for implanting an embryo (Claim 21). One of ordinary skill in the art would be either an engineer with a biomedical engineering background or a surgeon or other medical personnel.

6. Bergman is entitled "Medical Reproductive System." With respect to scope, Bergman discloses a computer-based interactive system that reproduces a medical examination by those using complex medical machinery, such as that used in an ultrasound examination. Col. 1, ll. 6-10. It can be used as a diagnostic tool or as a

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

simulator for training purposes. Col. 1, ll. 13-15. With respect to content, Bergman discloses that biological data are taken from a live patient and stored as ultrasound images (col. 5, ll. 30-31) along with data relating to the position of the ultrasound probe (col. 5, ll. 32-33). Using a simulated body and transmitter (col. 8, ll. 32-35), a simulated ultrasound probe is provided that is held by a trainee and manipulated (col. 8, ll. 45-49). The simulated ultrasound probe contains a sensor (receiver) connected to a simulated ultrasound unit. Col. 8, ll. 44-46. Signals received by the receiver in the probe include position data. Col. 8, ll. 65-67. The position data are used by a processor to reproduce a medical examination of the living body using the stored biological display data. Col. 9, ll. 10-14. With respect to differences between the claims on appeal and the cited art, Bergman displays previously collected ultrasound images of the actual patient (Claim 1), because no ultrasound image is being collected from the training session. Bergman does not disclose any opening in the simulated body being modified between training sessions, in order to change an echogenicity. Bergman discloses an ultrasound training system (Claim 1). One of ordinary skill in the art would be either an engineer with a biomedical engineering background or a physician or other medical personnel.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

ARGUMENT

Errors in Rejection Based on Gain in View of NPL#1 and Further in View of Cecchi

Claim 1

The Examiner erred in rejecting Claim 1 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established. There is no motivation that would lead one of ordinary skill in the art of Cecchi to modify the cited art to include at least one simulated patent skull suture. The cited art does not teach or suggest including a second material that can be visually identified in an ultrasound image and which prevents tactile detection during a training exercise.

The Examiner asserts that it would have been obvious to include the feature of including simulated patent skull sutures, as seen in NPL#1, in the Gain system, because it would enable the Gain system to better approximate the physiology of a human infant. Office Action dated 10/28/2008, p. 4, first full paragraph. Appellants have previously disagreed with the Examiner on this issue for the following reasons.

> Gain does NOT emphasize that fine anatomical details (such as sutures) are important in artificial craniums used for *mechanical tests for shock resistance*. Gain notes that models suitable for the study of anatomy are NOT suitable for mechanical crash studies. Gain indicates that what is needed is an artificial cranium and a prosthetic head produced from same cranium having the ***same mechanical behavior*** and ***shape characteristics*** as a fresh cranium and a real head respectively" (column 1, ll. 61-65 – emphasis added). Gain further explains that "shape characteristics"

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

means that the artificial cranium must have the same shape and dimensions as a real human cranium and also include the cavities corresponding to the natural cavities of a real human head (column 2, ll. 7-12). Gain also emphasizes determining equivalent resin thickness so that the compression strength at a given point of the artificial cranium is equal to the compression strength at the corresponding point of the fresh cranium (Gain, column 5, ll. 57-62). But, Gain then discloses that the thickness of the material constituting the artificial cranium differs from that of the real bone and that the internal cavities do not exactly reproduce the cavities of the fresh cranium and indicates that these dimensional differences are not important, so long as the mechanical properties are faithfully replicated (Gain, column 5, ll. 18-23). Thus, the approximate cranium mold 43, which comprises a lower part 54 and an upper part 56, as seen in Gain's FIGURE 5, is used to produce the artificial cranium that is sufficient for purposes of accident prevention studies, and fine details of anatomical structures are ignored. Office Action Response dated 1/22/2008, p. 12, ll. 11 – 28.

In other words, Gain does not teach or suggest that adding sutures to a cranium used for crash studies would provide any benefit. Significantly, there is simply no evidence indicating that sutures are at all relevant to the studies being performed by Gain. Office Action Response dated 1/22/2008, p. 13, ll. 1-3.

In addition, the Examiner asserts that the Gain reference provides a teaching of preventing tactile detection of a simulated patent skull sutures model, while enabling the simulated patent skull to be visually detected based upon an appearance of the

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

simulated patent skull suture in an ultrasound image of said model as disclosed in col. 11:50-55 "skin." Office Action dated 10/28/2008, p. 4, first partial paragraph. The Examiner further asserts that because the Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material, it would have been obvious to manipulate the density of the second material. Office Action dated 10/28/2008, p. 4, second full paragraph. The Examiner explains that doing so would enable the head model to have the correct echogenic properties, as taught by Cecchi. *Id.* Appellants have previously disagreed with the Examiner for the following reasons.

> The "*correct echogenic properties*" remark by the Examiner is significant. Only appellants, but none of the prior art references, define what the *correct echogenic properties* of a head model should be. Neither Gain nor NPL#1 require any particular *echogenic properties.* Gain requires that the material properties of the model realistically respond to mechanical stresses. The *echogenic properties* of the materials are irrelevant in achieving this goal. Manipulating the *echogenic properties* of the materials in Gain's model will not improve the model with respect to its intended purpose, i.e., realistically responding to mechanical stresses. Cecchi defines the *correct echogenic properties* for an embryonic catheter, but not for a medical model for training sonographers to detect craniosynostosis. The suggested combination is impermissibly based on hindsight, because hindsight is required to understand how the *correct echogenic properties* is important

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

in producing a head model, not the prior art. Amendment dated 1/28/2009, p. 15, ll. 1 – 10.

None of the cited art provides an equivalent to the specific structure underlined above. Even if Cecchi's manipulation of materials was included in a medical model, there would be no need for the second material to extend beyond the opening. Amendment dated 1/28/2009, p. 16, ll. 27 – 29.

Claim 21

Claim 21 has been rejected under 35 U.S.C. § 103(a), although no substantive reasons are set forth. Office Action dated 10/28/2008, Item 7, p.3.

Appellants assert that Claim 21 is patentable for at least the following reasons. First, there is no motivation to modify the cited art to include at least one simulated patent skull suture. In addition, the cited art does not teach or suggest a hypoechoic material that causes an echogenicity of the simulated skull suture to differ from that of portions of the model not corresponding to the simulated patent skull suture. Also, the cited art does not teach or suggest a filler material for selectively replacing the hypoechoic material. Appellants have previously provided the following remarks to explain why Claim 21 is patentable:

> Gain discloses a model made of different materials for evaluating mechanical stresses on the head during a crash (however, the different materials are selected so that the model realistically responds to mechanical stress, and the appearance of those materials in an ultrasound image is not relevant to Gain's intended function, nor is there any

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

description in Gain as to how those materials used by Gain would appear in an ultrasound image); NPL#1 discloses a model of an infant head including patent skull sutures; and Cecchi discloses modifying a distal portion of a catheter so that the distal portion can be more readily observed in an ultrasound image. The Examiner's rejection appears to assert that because Cecchi discloses that materials can be manipulated to provide a desired appearance in an ultrasound image, it would have been obvious to the artisan of ordinary skill to incorporate the patent skull sutures of NPL#1 into Gain, using materials selected such that the patent skull sutures are made of different materials than other portions of the model, so that the patent skull sutures are visible in an ultrasound image. Amendment dated 1/28/2009, p. 13, ll. 14-26.

Appellants respectfully disagree with this assertion for the following reasons. The cited art (Gain, NPL#1, and Cecchi) provides no evidence that the artisan of ordinary skill recognized that providing *a medical training model that could be used to train sonographers to detect craniosynostosis* represented a problem to be solved. While NPL#1 and Gain provide models that can be used as visual aids for medical training, and Gain's model is specifically constructed to realistically respond to the application of mechanical stresses, those models are not designed to be examined using ultrasound. It is appellants' position that applying Cecchi's manipulation of materials to control what can be observed in an ultrasound image to achieve a model for training sonographers to detect craniosynostosis represents a combination that would not have been obvious to the artisan of ordinary skill. Amendment dated 1/28/2009,

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

p. 13, line 28 - p. 14, line 6.

Claim 27

The Examiner erred in rejecting Claim 27 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established. The cited art does not teach or suggest a model that includes at least one simulated patent skull suture and does not teach or suggest at least one simulated fused skull suture. In addition, the cited art does not teach or suggest that simulated patent skull sutures are readily distinguishable from one another in an ultrasound image.

The Examiner asserts that it would have been obvious to include the feature of simulated patent skull sutures, as seen in NPL#1, in the Gain system, because doing so would enable the Gain system to better approximate the physiology of a human infant. Office Action dated 10/28/2008, p. 4, first full paragraph. Appellants have previously disagreed with the Examiner by stating that:

> Claim 27 therefore distinguishes over the cited art for substantially the same reasons as does Claim 1. Office Action Response dated 1/22/2008, p. 14, ll. 8-9.

For the sake of brevity, these reasons are not repeated here. Please see the arguments set forth above in traversing the rejection of Claim 1.

The Examiner has also cited to Gain's Figure 2 as providing a teaching of an adult-looking skull model with a fused skull suture. Office Action dated 10/28/2008, p. 19. The Examiner takes the position that it is common knowledge that different

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

skull bone in an adult human is characterized by fused skull sutures. *Id.* Appellants have previously responded that they do NOT agree with the Examiner's assertion for the following reasons.

> The Examiner appears to have overlooked a recitation in Claim 27 that is not taught or suggested by the cited references. Specifically, Claim 27 recites, "*a substantially life size model of a human head, said model including at least one simulated patent skull suture and* ***at least one simulated fused skull suture****, an echogenicity of each simulated patent skull suture enabling the simulated patent skull suture to be readily distinguishable from each simulated fused skull suture in an ultrasound image of said model, such that each simulated patent skull suture will appear dark in such an ultrasound image, and each simulated fused skull suture will appear bright in such an ultrasound image.*" (Emphasis added.) None of the references make any teaching or suggestion of including a simulated fused skull suture in a model of a skull, which is not surprising, since that condition is NOT considered a normal condition in an infant's or child's skull. Accordingly, it is further not surprising that none of the references teaches or suggests how such a simulated fused skull suture on a model of a skull might be visually detected in an ultrasound image of an ultrasound trainer, as recited in this claim. Office Action Response dated 7/18/2008, p. 13, ll. 8-20.
>
> Even if Gain were modified to include patent skull sutures because such sutures represent fine anatomical detail that should be incorporated into a model used for crash testing (and as discussed above appellants submit

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

that Gain ***does not teach or suggest*** that such fine anatomical details are needed), note that fused skull sutures represent an abnormality that appears to have no relationship to the crash testing for which Gain's models are to be used. There are many different anatomical abnormalities possible in human heads, and Gain simply does not teach or suggest that a head model used for crash test purposes should include any such abnormality. To modify Gain's model to include ***only*** the abnormality recited in appellants' claims, an abnormality having nothing to do with crash testing, but which is very relevant to appellants' ultrasound screening, appears to imperishably rely on hindsight. In other words, there does not appear to be any reasonable rationale for modifying Gain's model. Office Action Response dated 1/22/2008, p. 14, ll. 10-21.

Finally, no reference has been cited that teaches or suggests how simulated skull sutures can be readily distinguished in an ultrasound image. Appellants have previously pointed out to the Examiner that:

> ..it is further not surprising that none of the references teach or suggest how such a simulated fused skull suture on a model of a skull might be visually detected in an ultrasound image of an ultrasound trainer. Office Action Response dated 7/18/2008, p. 13, ll. 17-20.

Claim 52

The Examiner erred in rejecting Claim 52 under 35 U.S.C. § 103(a). Although no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7, p.3), appellants believe Claim 52 is patentable for at least the following reasons. There is no motivation to modify the cited art to include at least one simulated patent skull

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

suture. The cited art does not teach or suggest a model that includes at least one simulated patent skull suture that can be selectively modified to appear as a simulated fused skull suture. The cited art does not teach or suggest how to modify a skull suture such that the different simulated patent skull sutures can be readily distinguished from non suture portions of the model in an ultrasound image. In the interest of brevity, please see appellants' remarks directed to the traversal of the rejection of Claim 52 under different grounds, as discussed below.

Claim 53

The Examiner erred in rejecting Claim 53 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established. Although no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7, p.3), appellants believe Claim 53 is patentable for at least the following reasons. Again, there is no motivation to modify the cited art to include at least one simulated patent skull suture. In addition, the cited art does not teach or suggest that the simulated patent skull sutures can be reversibly modified. In the interest of brevity, please see appellants' further remarks directed to the traversal of the rejection of Claim 53 under different grounds, below.

Claim 54

The Examiner erred in rejecting Claim 54 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

Although no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7, p.3), appellants believe Claim 54 is patentable for at least the following reasons. The cited art does not teach or suggest either a simulated patent skull suture or a simulated fused skull suture. In addition, the cited art does not teach or suggest a third material that includes echogenic properties such that a simulated fused skull suture can be distinguished from a simulated patent skull suture in an ultrasound image. In the interest of brevity, please see appellants' further remarks directed to the traversal of the rejection of Claim 54 under different grounds, below.

Claim 57

The Examiner erred in rejecting Claim 57 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established. Although no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7, p.3), appellants believe Claim 57 is patentable for at least the following reasons. The cited art does not teach or suggest at least one opening corresponding to a simulated patent skull suture and at least one opening corresponding to a simulated fused skull suture. In addition, the cited art does not teach or suggest a model being fabricated from a first material and that a second material disposed within each opening corresponding to a simulated patent skull suture will perform so that each opening corresponding to the simulated patent skull suture can be distinguished from the first material in an ultrasound. In addition, the cited art does not teach or suggest a third

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

material that includes echogenic properties such that at least one opening corresponding to a simulated fused skull suture can be distinguished from a simulated patent skull suture in an ultrasound image. In the interest of brevity, please see appellants' further remarks directed to the traversal of the rejection of Claim 57 under different grounds, below.

Claim 58

The Examiner erred in rejecting Claim 58 under 35 U.S.C. § 103(a) because a *prima facie* case of obviousness has not been established. Although no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7, p.3), appellants believe Claim 58 is patentable for at least the following reasons. The cited art does not teach or suggest a plurality of openings each corresponding to a simulated patent skull suture. The cited art does not teach or suggest a model including a filler material that can be selectively added. In the interest of brevity, please see appellants' further remarks directed to the traversal of the rejection of Claim 58 under different grounds, below.

Errors in Rejection Based on Gain in View of NPL#1 in view of Bergman and Further in View of Cecchi

Claim 21

The Examiner erred in rejecting Claim 21 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established. There is

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

no motivation to modify the cited art to include at least one simulated patent skull suture. In addition, the cited art does not teach or suggest a hypoechoic material that causes an echogenicity of the simulated skull suture to differ from that of portions of the model not corresponding to the simulated patent skull suture. The cited art does not teach or suggest a filler material for selectively replacing the hypoechoic material.

The Examiner asserts that it would have been obvious to include the feature of a simulated patent skull suture, as seen in NPL#1, in the Gain system, because doing so would enable the Gain system to better approximate the physiology of a human infant. Office Action dated 10/28/2008, p. 11, first full paragraph. Appellants have previously disagreed with the Examiner and stated that:

> Claim 21 therefore distinguishes over the cited art for substantially the same reasons as does Claim 1. Office Action Response dated 1/22/2008, p. 13, ll. 11 – 12.

For the sake of brevity, these reasons are not being reproduced here. Instead, please see the reasons given above in regard to appellants' traversal of the rejection of Claim 1.

The Examiner asserts that the Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Office Action dated 10/28/2008, p. 11, second full paragraph. The Examiner concludes that it would have been obvious to manipulate the density of the second material because it would enable the head model

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

to have the correct echogenic properties, as taught by Cecchi. *Id.* Appellants have previously disagreed with the Examiner on this point. In the interest of brevity, these reasons are not now repeated. Instead, please see the remarks set forth above.

The Examiner also asserts that although Gain fails to provide a teaching that reads on subparagraph (c), which provides for selectively modifying the model between training sessions, Bergman provides this teaching in col. 8, ll. 35-50. Office Action dated 10/28/2008, p. 11, last paragraph. – p. 12, first paragraph. The Examiner concludes that it would have been obvious to do so in order to provide training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies, as disclosed in Bergman at col. 2, ll. 1-5. *Id.* Appellants have previously disagreed with the Examiner on this point because:

> None of the art cited by the Examiner teaches or suggests filling an opening in a model of a skull with a filler material that has an echogenicity that is generally similar to that of the other portions of the model, where the model can be modified between training sessions by removing the filler material from at least one opening and adding the filler material to a different opening. This approach is important so that a student who has gone through one training session will not simply learn where the fused skull suture is located on the model skull and be able to use that knowledge to indicate where the fused skull suture is located in a subsequent training session. By providing means to change the location of the simulated fused skull suture between training sessions, the usefulness of the model is greatly enhanced. This functionality is not

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

obvious in view of the art and is clearly supported in appellants' specification at p. 16, line 25 Amendment dated 1/28/2009, p. 17, line 22 – p. 18, line 1.

In addition, appellants have previously responded with the following argument.

Bergman discloses an ultrasound training model, based on a computer in which are stored actual ultrasound images, a mannequin, and a sensor (a position sensor capable of accurately determining the sensor's position relative to the mannequin) that simulates an ultrasound probe. The student moves the sensor relative to the mannequin, and based on the sensor's position the computer displays a previously obtained ultrasound image corresponding to the position of the sensor relative to the mannequin. Note that no ultrasound image is actually being collected during the training session; instead, previously collected ultrasound images of actual humans (and not of the mannequin) are displayed. Amendment dated 1/28/2009, p. 15, ll. 15-22.

With respect to *"selectively modifying a model between training sessions,"* the recorded ultrasound images presumably could be modified between sessions (although it does not appear that Bergman discloses such a modification), however, appellants cannot find any mention of an opening in the mannequin being modified between sessions to change the echogenicity of the opening. Further, such a modification would not be logical, since the *echogenic properties* of the mannequin are irrelevant for its intended use, because no actual ultrasound data is being collected from the mannequin (only a relative position, so previously record

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

ultrasound images obtained from a real patient can be displayed). Amendment dated 1/28/2009, p. 15, ll. 23-29.

The Examiner has specifically cited to 8:35-50 of Bergman as being particularly relevant. Respectfully, that portion, reproduced below, does not appear relevant to the pending claims, and ***does not*** disclose "*selectively modifying a model between training sessions* by *enabling a filler material to be added to an opening.*" Amendment dated 1/28/2009, p.16, ll. 1–4.

Claim 52

The Examiner erred in rejecting Claim 52 because a *prima facie* case of obviousness has not been established.. There is no motivation to modify the cited art to include at least one simulated patent skull suture. The cited art does not teach or suggest a model that includes at least one simulated patent skull suture that can be selectively modified to appear as a simulated fused skull suture. The cited art does not teach or suggest how to modify such that the different simulated patent skull sutures can be readily distinguished from a non suture portion of the model in an ultrasound image.

The Examiner asserts that it would have been obvious to include the feature of having simulated patent skull sutures, as seen in NPL#1, in the Gain system, because doing so would enable the Gain system to better approximate the physiology of a human infant. Office Action dated 10/28/2008, p. 15, first paragraph.

Appellants have previously disagreed with the Examiner on this rejection, by

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

noting that "Claims 52 ... therefore distinguish over the cited art for substantially the same reasons as does Claim 1." Office Action Response dated 1/22/2008, p. 15, ll. 4-5. For the sake of brevity, these reasons are not repeated here. Instead, please see the remarks given above.

Furthermore, the Examiner asserts that although Gain does not teach that a skull suture can be selectively modified, Bergman provides this teaching and cites to col. 8, ll. 35-50. Office Action dated 10/28/2008, p. 15. The Examiner concludes that it would have been obvious to include the feature of a skull suture that can be selectively modified in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies as disclosed in col. 2, ll. 1-5. *Id.* Appellants have previously disagreed with the Examiner on this point for the following reasons.

> The Bergman reference (U.S. Patent No. 5,609,485) ***DOES NOT*** disclose *selectively modifying a model between training sessions* by *enabling a filler material to be added to an opening.* Accordingly, the cited combination of Bergman and Gain is not a valid rejection. Amendment dated 1/28/2009, p. 19, ll. 7-11.

For the sake of brevity, the reasons will not be repeated. Instead, please see above at page 27, line 9 through page 28, line 6.

Also, the Examiner asserts that although Gain is silent on echogenicity, the difference in density of the first material epoxy resin and the second material – oil and

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

silicon mixture – would have resulted in a difference in echogenicity such that the materials can be readily distinguished in an ultrasound image of said model. Office Action dated 10/28/2008, p. 14. Appellants have previously disagreed with the Examiner for the following reasons.

> The prior art references ... do not in any way indicate how differences in echogenicity between the simulated fused skull suture and the simulated patent skull suture might be used to distinguish between the two in an ultrasound image." Office Action Response dated 7/18/2008, p. 14, ll. 2-5).

In addition, appellants have previously noted:

> The Examiner has asserted that the materials disclosed by Gain have different echogenic properties and thus would be distinguishable in an ultrasound image. The Examiner has not provided any evidentiary support for this. Applicants are not disputing that materials have echogenic properties, only that the materials disclosed by Gain would be sufficient to enable simulated fused and patent skull sutures to be differentiated. Some of the materials (the polymers) disclosed by Gain are similar to materials disclosed by applicants for simulating a fused skull suture (elastomers), however, Gain does not disclose any material similar to the starch/glue mixture used to simulate the patent skull sutures. Absent any actual evidence that the difference in echogenicity of oil/silicone mixtures and epoxy resin is sufficient that such materials can be used to generate a fused skull suture and a patent skull suture that can be distinguished in an ultrasound image, this rejection is unwarranted. Amendment dated 1/28/2009, p. 18, line 26 - p. 19, line 6.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

Claim 53

The Examiner erred in rejecting Claim 53 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established. There is no motivation to modify the cited art to include at least one simulated patent skull suture. In addition, the cited art does not teach or suggest that the simulated patent skull sutures can be reversibly modified.

The Examiner asserts that it would have been obvious to include the feature of having simulated patent skull sutures as seen in NPL#1 in the Gain system, because it would enable the Gain system to better approximate the physiology of a human infant. Office Action dated 10/28/2008, p. 16, first full paragraph. Appellants have previously disagreed with the Examiner for the following reasons.

> The Examiner again relies upon Gain and the first NPL reference for teaching the recitation of Claim 53... it will now be apparent that the claim recites a novel and non-obvious approach that is not taught or suggested by the prior art references cited, since none of these references even refer to including or detecting a simulated skull suture .... Office Action Response dated 7/18/2008, p.14, ll. 15-17.

In addition, appellants have previously responded to explain why Gain does not teach or suggest adding a suture to a model. However, for the sake of brevity, these reasons are not being repeated here. Instead, please see the remarks above:

In addition, the Examiner asserts that although Gain does not teach that a skull

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

suture can be selectively modified, Bergman provides this teaching, and the Examiner cites to col. 8, ll. 35-50. Office Action dated 10/28/2008, p. 16. The Examiner concludes that it would have been obvious to include the feature of a skull suture that can be selectively modified in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies as disclosed in col. 2, ll. 1-5. Office Action dated 10/28/2008, pp. 16-17.

Appellants have previously disagreed with the Examiner on this point because the cited references "do not discuss any manner in which a simulated patent skull suture might be ***reversibly*** modified to produce a simulated fused skull suture." Office Action Response dated 7/18/2008, p. 14, ll. 16-17.

In addition, appellants have previously disagreed with the Examiner because "as discussed above in detail, Bergman does not disclose that element." Amendment dated 1/28/2009, p.19, ll. 23. "That element" refers to the following discussion.

> Bergman discloses an ultrasound training model, based on a computer in which are stored actual ultrasound images, a mannequin, and a sensor (a position sensor capable of accurately determining the sensor's position relative to the mannequin) that simulates an ultrasound probe. The student moves the sensor relative to the mannequin, and based on the sensor's position the computer displays a previously obtained ultrasound image corresponding to the position of the sensor relative to the mannequin. Note that no ultrasound image is actually being collected during the training session, rather previously collected ultrasound images

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

of actual humans (and not of the mannequin) are displayed. Amendment dated 1/28/2009, p. 15, ll. 15-22.

With respect to *selectively modifying a model between training sessions*, presumably the recorded ultrasound images could be modified between sessions (although it does not appear that Bergman discloses such a modification), however, applicants cannot find any mention of an opening in the mannequin being modified between sessions to change the echogenicity of the opening. Further, such a modification would not be logical, as the *echogenic properties* of the mannequin are irrelevant, as no actual ultrasound data is being collected from the mannequin (only a relative position, so previously record ultrasound images obtained from a real patient can be displayed). Amendment dated 1/28/2009, p. 15, ll. 15-29.

Claim 54

The Examiner erred in rejecting Claim 54 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established. The cited art does not teach or suggest either a simulated patent skull suture or a simulated fused skull suture. In addition, the cited art does not teach or suggest a third material that includes echogenic properties, such that a simulated fused skull suture can be distinguished from a simulated patent skull suture in an ultrasound image.

The Examiner asserts that it would have been obvious to include the feature of having simulated patent skull sutures, as seen in NPL#1, in the Gain system, because doing so would enable the Gain system to better approximate the physiology of a

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

human infant. Office Action dated 10/28/2008, p. 17, second full paragraph. Appellants have NOT previously disagreed with the Examiner on this point. However, similar to their traversal set forth with respect to other independent claims in the above-identified application, they do now disagree. For the sake of brevity, these reasons are not being repeated here. Instead, please see the remarks above.

Further, no reference has been cited that teaches or suggests a fused simulated patent skull suture, and appellants have previously responded that they do NOT agree with the Examiner's rejection because:

> None of the references teach a simulated fused skull suture .... Office Action Response dated 7/18/2008, p. 14, ll. 29-30.

The Examiner also asserts that the Bergman reference provides a teaching of a third material, at col. 8, ll.35-50. Office Action dated 10/28/2008, p. 18, last full paragraph. The Examiner concludes that the recitation in appellants' paragraph (b) of Claim 54, regarding the third material being disposed within each opening corresponding to a simulated fused skull suture wherein the echogenicity of the third material is distinguishable from the echogenicity of the second material in order for each simulated fused skull suture to be distinguished from each simulated patent skull suture in an ultrasound image, is obvious in view of Bergman. *Id.* He reaches this conclusion because Bergman teaches selectively modifying the model, with the motivation being to provide training on a simulated patient. *Id.* Appellants have

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

previously disagreed with the Examiner on this point, because:

> None of the references ...teach or suggest that a third material disposed in an opening in a model of a skull is used for a simulated fused skull suture. There is also no teaching or suggestion that the third material disposed in an opening of a model of a skull might have an echogenicity that is readily distinguished from an echogenicity of a second material used in the simulated patent skull sutures, so that the simulated fused skull suture can be readily distinguished from each simulated patent skull suture in an ultrasound image of the model. Office Action Response dated 7/18/2008, p. 14, line 29-p. 15, line 5.

Claim 57

The Examiner erred in rejecting Claim 57 under 35 U.S.C. § 103(a) over the cited art because a *prima facie* case of obviousness has not been established. The cited art does not teach or suggest at least one opening corresponding to simulated patent skull suture and at least one opening corresponding to a simulated fused skull suture. In addition, the cited art does not teach or suggest a model being fabricated from a first material, or that a second material disposed within each opening corresponding to a simulated patent skull suture will perform so that each opening corresponding to the simulated patent skull suture can be distinguished from the first material in an ultrasound image. In addition, the cited art does not teach or suggest a third material that includes echogenic properties such that at least one opening corresponding to a simulated fused skull suture can be distinguished from a simulated

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

patent skull suture in an ultrasound image.

The Examiner asserts that it would have been obvious to include the feature of having simulated patent skull sutures, as seen in NPL#1, in the Gain system, because it would enable the Gain system to better approximate the physiology of a human infant. Office Action dated 10/28/2008, p. 17, second full paragraph. Appellants have NOT previously noted that they disagree with the Examiner on this point. However, for reasons similar to their traversal set forth with respect to other independent claims in the above-identified application, they do indeed disagree. These remarks are not being repeated here for the sake of brevity. Instead, please see the remarks above.

No reference has been cited that teaches or suggests a fused simulated patent skull suture. Appellants have previously responded that they do NOT agree with the Examiner, because "None of the references teach a simulated fused skull suture ...." Office Action Response dated 7/18/2008, p. 14, ll. 29-30.

In addition, the Examiner asserts that the Bergman reference provides a teaching of a third material in col. 8, ll.35-50. Office Action dated 10/28/2008, p. 18, last full paragraph. The Examiner concludes that the recitation in appellants' paragraph (b) of Claim 57, regarding the third material being disposed within each opening corresponding to a simulated fused skull suture wherein the echogenicity of the third material is distinguishable from the echogenicity of the second material in order for each simulated fused skull suture to be distinguished from each simulated

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

patent skull suture in an ultrasound image, is obvious in view of Bergman. *Id.* He justifies this assertion by stating that Bergman teaches selectively modifying the model, with the motivation being to provide training on a simulated patient. *Id.* Appellants have previously disagreed on this point with the Examiner. These reasons will not be repeated for the sake of brevity, please see above, page 35, lines 7-13.

Claim 58

Claim 58 has been rejected under 35 U.S.C. § 103(a), although no substantive reasons are set forth. Office Action dated 10/28/2008, Item #8, p. 9. Again, there is no motivation to modify the cited art to include at least one simulated patent skull suture. In the interest of brevity, please see the reasons set forth above. In addition, there are no references cited that disclose selectively adding a filler material to at least one opening, in order to create a simulated fused skull suture.

For at least the reasons set forth above, appellants respectfully request that the Board of Patent Appeals and Interferences overrule the Examiner's rejection of all of the claims. The patentability of each dependent claim is not necessarily separately addressed in detail. However, appellants' decision NOT to discuss the differences between the cited art and each dependent claim should not be considered as an admission that appellants concur with the Examiner's conclusion that these dependent claims are not patentable over the disclosure in the cited references. Similarly, appellants' decision not to discuss differences between the prior art and every claim

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

element, or every comment made by the Examiner, should not be considered as an admission that appellants concur with the Examiner's interpretation and assertions regarding those claims. Indeed, appellants believe that all of the dependent claims patentably distinguish over the references cited. In any event, a specific traverse of the rejection of each dependent claim is not required, since dependent claims are patentable for at least the same reasons as the independent claims from which the dependent claims ultimately depend. Because dependent claims inherently include each element recited in the independent claim upon which they ultimately depend, each claim depending upon its respective independent claim is patentable for at least the same reasons as those discussed above. Accordingly, appellants respectfully request that the Board of Patent Appeals and Interferences overrule the Examiner's rejection of all of the dependent claims as well as of the independent claims.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

APPENDIX

CLAIMS SECTION

1. (Rejected) A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life size model of a human infant head, said model being at least in part fabricated from a first material, said model including at least one simulated patent skull suture comprising a second material and a scalp portion in which each simulated patent skull suture is disposed, such that the scalp portion of the model is covered with a layer of the second material, the second material extending beyond an opening in the first material defining the simulated patent skull suture and covering at least a portion of the first material, to prevent the simulated patent skull suture from being identified tactilely, the second material having an echogenicity substantially different than an echogenicity of said first material, such that each simulated patent skull suture can be readily distinguished in an ultrasound image of said model.

2. (Canceled)

3. (Canceled)

4. (Rejected) The medical simulator of Claim 1, wherein the second material is hypoechoic relative to the first material.

5. (Rejected) The medical simulator of Claim 1, wherein the echogenicity of the second material is lower than the echogenicity of the first material, such that in an

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

ultrasound image of the model, portions of the model corresponding to the first material appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

6. (Canceled)

7. (Rejected) The medical simulator of Claim 1, wherein the second material comprises a mixture of a starch and a glue.

8. (Rejected) The medical simulator of Claim 7, wherein the glue is a casein-based glue.

9. (Rejected) The medical simulator of Claim 7, wherein the glue is a synthetic resin-based glue.

10. (Rejected) The medical simulator of Claim 1, wherein at least one simulated patent skull suture corresponds to at least one of a simulated patent coronal skull suture and a simulated patent lambdoid skull suture, and wherein each opening corresponding to a simulated patent coronal skull suture is beveled, and each opening corresponding to a simulated patent lambdoid skull suture is beveled.

11. (Rejected) The medical simulator of Claim 1, wherein at least one opening corresponding to a simulated patent skull suture corresponds to at least one of a simulated patent sagittal skull suture and a simulated patent metopic skull suture, so that opposed walls of each opening corresponding to a simulated patent sagittal skull suture exhibit an end-to-end configuration, and opposed walls of each opening

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

corresponding to a simulated patent metopic skull suture exhibit an end-to-end configuration.

12. (Rejected) The medical simulator of Claim 1, further comprising at least one simulated fused skull suture.

13. (Rejected) The medical simulator of Claim 12, wherein each simulated fused skull suture comprises said first material.

14. (Rejected) The medical simulator of Claim 12, wherein each simulated fused skull suture comprises an opening within said first material, each opening corresponding to a simulated fused skull structure in which a third material is disposed, an echogenicity of the third material being substantially distinguishable from the echogenicity of the second material, so that each opening corresponding to a simulated fused skull suture can be readily distinguished from an opening corresponding to a simulated patent skull suture in an ultrasound image of said model.

15. (Rejected) The medical simulator of Claim 14, wherein the echogenicity of the third material is substantially similar to the echogenicity of the first material, such that in an ultrasound image of the model, portions of the model comprising the first material are not readily distinguishable from portions of the model comprising the third material.

16. (Rejected) The medical simulator of Claim 14, wherein the third material comprises a synthetic elastomer.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

17. (Rejected) The medical simulator of Claim 16, wherein the synthetic elastomer comprises dimethyl siloxane, hydroxy-terminated polymers, and silica.

18. (Rejected) The medical simulator of Claim 12, further comprising an opaque layer configured to cover each simulated patent skull suture and each simulated fused skull suture, so that a trainee cannot readily visually determine whether a specific skull suture is patent or fused by visually inspecting the model.

19. (Rejected) The medical simulator of Claim 1, further comprising an opaque layer configured to cover a scalp portion of the model, so that a trainee cannot readily visually locate each simulated patent skull suture by visually inspecting the model.

20. (Rejected) The medical simulator of Claim 1, wherein a doll's head is utilized for the substantially life size model of a human head.

21. (Rejected) A medical simulator adapted to be used to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising:

(a) a substantially life size model of a human infant head, said model including a plurality of openings;

(b) a solid or semi-solid hypoechoic material being included in each opening so that the opening corresponds to a simulated patent skull suture, wherein the hypoechoic material causes an echogenicity of the simulated skull suture to differ

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

from that of portions of the model not corresponding to the simulated patent skull suture, the difference enabling each simulated patent skull suture to be identified in an ultrasonic image; and

(c) a filler material for selectively replacing the hypoechoic material included in at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material replaces the hypoechoic material simulates a fused skull suture in an ultrasonic image, the model being modifiable between training sessions by replacing the hypoechoic material with the filler material in at least one opening.

22. (Rejected) The medical simulator of Claim 21, wherein when the medical simulator is imaged using ultrasound, the hypoechoic material produces a relatively dark image, whereas adjacent portions of the model produce a relatively bright image, such that each simulated patent skull suture appears in the ultrasound image as a relatively dark area surrounded by relatively brighter areas.

23. (Rejected) The medical simulator of Claim 21, wherein said model is fabricated from a first material, such that the solid or semi-solid hypoechoic material included in each opening corresponding to a simulated patent skull suture represents a second material, an echogenicity of the second material being substantially different than the echogenicity of the first material, so that each opening corresponding to a

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

simulated patent skull suture can be readily distinguished from the first material in an ultrasound image of said model.

24. (Rejected) The medical simulator of Claim 23, wherein the echogenicity of the second material is lower than the echogenicity of the first material, such that in an ultrasound image of the model, portions of the model comprising the first material will appear relatively bright, while portions of the model comprising the second material will appear relatively dark.

25. (Rejected) The medical simulator of Claim 23, wherein the filler material for simulating a fused skull suture comprises a third material, an echogenicity of the third material being substantially different than the echogenicity of the second material, so that each opening corresponding to a simulated fused skull suture can be readily distinguished from an opening corresponding to a simulated patent skull suture in an ultrasound image of said model.

26. (Rejected) The medical simulator of Claim 21, wherein:

(a) each opening corresponding to a simulated patent skull suture intended to represent a patent coronal skull suture is beveled;

(b) each opening corresponding to a simulated patent skull suture intended to represent a patent lambdoid skull suture is beveled;

(c) each opening corresponding to a simulated patent skull suture intended to represent a patent sagittal skull suture is disposed such that opposed walls

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

of the opening exhibit an end-to-end configuration; and

(d) each opening corresponding to a simulated patent skull suture intended to represent a patent metopic skull suture is disposed such that opposed walls of the opening exhibit an end-to-end configuration.

27. (Rejected) An ultrasound trainer configured to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound; comprising a substantially life size model of a human infant head, said model including at least one simulated patent skull suture and at least one simulated fused skull suture, an echogenicity of each simulated patent skull suture enabling the simulated patent skull suture to be readily distinguishable from each simulated fused skull suture in an ultrasound image of said model, such that each simulated patent skull suture will appear dark in such an ultrasound image, and each simulated fused skull suture will appear bright in such an ultrasound image.

28.-51. (Canceled)

52. (Rejected) A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life-size model of a human infant head, said model including two eyes, a mouth, two ears, and at least one simulated patent skull suture that can be selectively modified to appear as a simulated fused skull suture, a difference in echogenicity of each simulated patent skull suture and each simulated fused skull suture enabling each

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

simulated patent skull suture to be readily distinguishable from non suture portions of the model and from each simulated fused suture in an ultrasound image of said model.

53. (Rejected) A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life size model of a human head, said model including a plurality of simulated patent skull sutures, an echogenicity of each simulated patent skull suture enabling the simulated patent skull suture to be readily distinguishable in an ultrasound image of said model, such that each simulated patent skull suture will appear dark in such an ultrasound image, whereas adjacent portions of said model will appear bright in such an ultrasound image; and, further comprising means for reversibly modifying one or more selected simulated patent skull sutures to create one or more simulated fused skull sutures that can readily be detected in an ultrasound image, wherein each simulated fused skull suture will appear bright in the ultrasound image, like the portions of the model that are adjacent to the simulated patent skull sutures.

54. (Rejected) A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life size model of a human head, said model being at least in part fabricated from a first material, said model including:

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

(a) at least one simulated patent skull suture being at least in part fabricated from a second material, said second material comprising at least one of a solid and a semi-solid, an echogenicity of said second material being substantially different than an echogenicity of said first material, such that each simulated patent skull suture can be readily distinguished in an ultrasound image of said model; and

(b) at least one simulated fused skull suture, wherein each simulated fused skull suture comprises an opening within said first material, a third material being disposed within each opening corresponding to a simulated fused skull structure, an echogenicity of the third material being substantially distinguishable from the echogenicity of the second material, so that each simulated fused skull suture can be readily distinguished from each simulated patent skull suture in an ultrasound image of said model.

55. (Rejected) The medical simulator of Claim 54, wherein the echogenicity of the third material is substantially similar to the echogenicity of the first material, such that in an ultrasound image of the model, portions of the model comprising the first material are not readily distinguishable from portions of the model comprising the third material.

56. (Rejected) The medical simulator of Claim 54, wherein the third material comprises a synthetic elastomer.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

57. (Rejected) A medical simulator adapted to be used to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising:

(a) a substantially life size model of a human head, said model including at least one opening corresponding to a simulated patent skull suture, a solid or semi-solid hypoechoic material being disposed within each such opening to enhance a difference in an echogenicity of the simulated skull suture relative to that of portions of the model not corresponding to the simulated patent skull suture, the difference enabling each simulated patent skull suture to be identified in an ultrasonic image, said model being fabricated from a first material, such that the solid or semi-solid hypoechoic material disposed within each opening corresponding to a simulated patent skull suture represents a second material, an echogenicity of the second material being substantially different than the echogenicity of the first material, so that each opening corresponding to a simulated patent skull suture can be readily distinguished from the first material in an ultrasound image of said model; and

(b) at least one opening corresponding to a simulated fused skull suture, a third material being disposed within each opening corresponding to a simulated fused skull suture, an echogenicity of the third material being substantially different than the echogenicity of the second material, so that each opening corresponding to a simulated fused skull suture can be readily distinguished from an

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

opening corresponding to a simulated patent skull suture in an ultrasound image of said model.

58. (Rejected) A medical simulator adapted to be used to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising:

(a) a substantially life size model of an infant head, said model including a plurality of openings each corresponding to a simulated patent skull suture, a hypoechoic material being disposed within the opening to enhance a difference in an echogenicity of the simulated skull suture relative to that of portions of the model not corresponding to the simulated patent skull suture, the difference enabling each simulated patent skull suture to be identified in an ultrasonic image; and

(b) a first filler material that can be selectively added to at least one of the plurality of openings by a user, said first filler material having an echogenicity about equal to that of the portions of the model not corresponding to a simulated patent skull suture, such that when the first filler material is added to at least one opening, the first filler material in the opening creates a simulated fused skull suture.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

CLAIMS SUPPORT AND DRAWING ANALYSIS SECTION

1. (Rejected) A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life size model {Fig. 1A, element 10; paragraph 0041} of a human infant head, said model being at least in part fabricated from a first material {plastic material of paragraph 0045, ll. 1-2}, said model including at least one simulated patent skull suture {Fig. 1A, element 12; paragraph 0041} comprising a second material {GOOOZE™ or mixture of starch and glue; paragraph 0045, ll. 11-14} and a scalp portion in which each simulated patent skull suture is disposed, such that the scalp portion of the model is covered with a layer of the second material {paragraph 0078, ll. 14-17}, the second material extending beyond an opening {paragraph 0025} in the first material defining the simulated patent skull suture and covering at least a portion of the first material, to prevent the simulated patent skull suture from being identified tactilely {paragraph 0052, ll. 5-8}, the second material having an echogenicity substantially different than an echogenicity of said first material {paragraph 0050, ll. 3-4}, such that each simulated patent skull suture can be readily distinguished in an ultrasound image of said model {paragraph 0050, ll. 12-13, paragraph 0015, ll. 1-3}.

21. (Rejected) A medical simulator adapted to be used to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising:

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

(a) a substantially life size model. {Fig. 1A, element 10; paragraph 0041} of a human infant head, said model including a plurality of openings {paragraph 0025};

(b) a solid or semi-solid hypoechoic material {GOOOZE™ or mixture of starch and glue; paragraph 0045, ll. 11-14; paragraph 0051, ll. 16-18} being included in each opening so that the opening corresponds to a simulated patent skull suture {Fig. 1A, element 12; paragraph 0041}, wherein the hypoechoic material causes an echogenicity of the simulated skull suture to differ from that of portions of the model not corresponding to the simulated patent skull suture {paragraph 0051, ll. 10-15}, the difference enabling each simulated patent skull suture to be identified in an ultrasonic image {paragraph 0051, ll. 19-24}; and

(c) a filler material {synthetic moldable polymer; paragraph 0058} for selectively replacing {paragraph 0057, line 13} the hypoechoic material included in at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture {paragraph 0055, ll. 16-22}, so that each opening in which the filler material replaces the hypoechoic material simulates a fused skull suture {paragraph 0055, ll. 16-22} in an ultrasonic image, the model being modifiable between training sessions by replacing the hypoechoic material with the filler material in at least one opening {paragraph 0057, ll. 17-21}.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

27. (Rejected) An ultrasound trainer configured to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound; comprising a substantially life size model {Fig. 1A, element 10; paragraph 0041} of a human infant head, said model including at least one simulated patent skull suture {Fig. 1A, element 12; paragraph 0041} and at least one simulated fused skull suture {paragraph 0055, ll. 16-20}, an echogenicity of each simulated patent skull suture enabling the simulated patent skull suture to be readily distinguishable from each simulated fused skull suture in an ultrasound image of said model {paragraph 0055, ll. 16-22}, such that each simulated patent skull suture will appear dark {paragraph 0071, ll. 6-7} in such an ultrasound image, and each simulated fused skull suture will appear bright in such an ultrasound image {paragraph 0055, ll. 22-26}.

52. (Rejected) A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life-size model {Fig. 1A, element 10; paragraph 0041} of a human infant head, said model including two eyes, a mouth, two ears {paragraph 0068}, and at least one simulated patent skull suture {Fig. 1A, element 12; paragraph 0041} that can be selectively modified to appear as a simulated fused skull suture {paragraph 0057, ll. 11-16}, a difference in echogenicity of each simulated patent skull suture and each simulated fused skull suture enabling each simulated patent skull suture to be readily

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

distinguishable from non suture portions of the model and from each simulated fused suture in an ultrasound image of said model {paragraph 0055, ll. 16-22}.

53. (Please refer to the means plus function analysis section for this claim)

54. (Rejected) A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life size model {Fig. 1A, element 10; paragraph 0041} of a human head, said model being at least in part fabricated from a first material {plastic material of paragraph 0045, ll. 1-2}, said model including:

(a) at least one simulated patent skull suture {Fig. 1A, element 12; paragraph 0041} being at least in part fabricated from a second material {GOOOZE™ or mixture of starch and glue; paragraph 0045, ll. 11-14}, said second material comprising at least one of a solid and a semi-solid, an echogenicity of said second material being substantially different than an echogenicity of said first material {paragraph 0050, ll. 3-4}, such that each simulated patent skull suture can be readily distinguished in an ultrasound image of said model {paragraph 0050, ll. 12-13, paragraph 0015, ll. 1-3}; and

(b) at least one simulated fused skull suture {paragraph 0055, ll. 16-22}, wherein each simulated fused skull suture comprises an opening {paragraph 0025} within said first material, a third material {SILLY PUTTY™, paragraph 0058} being disposed within each opening corresponding to a simulated fused skull

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

structure, an echogenicity of the third material being substantially distinguishable from the echogenicity of the second material {paragraph.0066, ll. 1-4}, so that each simulated fused skull suture can be readily distinguished from each simulated patent skull suture in an ultrasound image of said model {paragraph.0066, ll. 4-6}.

57. (Rejected) A medical simulator adapted to be used to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising:

(a) a substantially life size model {Fig. 1A, element 10; paragraph 0041} of a human head, said model including at least one opening {paragraph 0025} corresponding to a simulated patent skull suture {Fig. 1A, element 12; paragraph 0041}, a solid or semi-solid hypoechoic material {GOOOZE™ or mixture of starch and glue; paragraph 0045, ll. 11-14; paragraph 0051, ll. 16-18} being disposed within each such opening to enhance a difference in an echogenicity of the simulated skull suture relative to that of portions of the model not corresponding to the simulated patent skull suture {paragraph 0051, ll. 10-15}, the difference enabling each simulated patent skull suture to be identified in an ultrasonic image {paragraph 0051, ll. 19-24}, said model being fabricated from a first material {plastic material of paragraph 0045, ll. 1-2}, such that the solid or semi-solid hypoechoic material disposed within each opening corresponding to a simulated patent skull suture represents a second material {GOOOZE™ or mixture of starch and glue; paragraph 0045, ll. 11-14}, an

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

echogenicity of the second material being substantially different than the echogenicity of the first material {paragraph 0050, ll. 3-4}, so that each opening corresponding to a simulated patent skull suture can be readily distinguished from the first material in an ultrasound image of said model {paragraph 0050, ll. 12-13, paragraph 0015, ll. 1-3}; and

(b) at least one opening corresponding to a simulated fused skull suture {paragraph 0055, ll. 16-22}, a third material {SILLY PUTTY™, paragraph 0058} being disposed within each opening corresponding to a simulated fused skull suture, an echogenicity of the third material being substantially different than the echogenicity of the second material {paragraph.0066, ll. 1-4}, so that each opening corresponding to a simulated fused skull suture can be readily distinguished from an opening corresponding to a simulated patent skull suture in an ultrasound image of said model {paragraph.0066, ll. 4-6}.

58. (Rejected) A medical simulator adapted to be used to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising:

(a) a substantially life size model {Fig. 1A, element 10; paragraph 0041} of an infant head, said model including a plurality of openings each corresponding to a simulated patent skull suture {Fig. 1A, element 12; paragraph 0041}, a hypoechoic material being disposed within the opening to enhance a

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

difference in an echogenicity of the simulated skull suture relative to that of portions of the model not corresponding to the simulated patent skull suture {paragraph 0051, ll. 10-15}, the difference enabling each simulated patent skull suture to be identified in an ultrasonic image {paragraph 0051, ll. 19-24}; and

(b) a first filler material {synthetic moldable polymer; paragraph 0058} that can be selectively added to at least one of the plurality of openings by a user, said first filler material having an echogenicity about equal {paragraph 0056, ll. 1-4} to that of the portions of the model not corresponding to a simulated patent skull suture {Fig. 1A, element 12; paragraph 0041}, such that when the first filler material is added to at least one opening, the first filler material in the opening creates a simulated fused skull suture {paragraph 0056, ll. 4-9}.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

MEANS PLUS FUNCTION ANALYSIS SECTION

53. (Rejected) A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life size model {Fig. 1A, element 10; paragraph 0041} of a human head, said model including a plurality of simulated patent skull sutures {Fig. 1A, element 12; paragraph 0041}, an echogenicity of each simulated patent skull suture enabling the simulated patent skull suture to be readily distinguishable in an ultrasound image of said model {paragraph 0055, ll. 16-22}, such that each simulated patent skull suture will appear dark {paragraph 0071, ll. 6-7} in such an ultrasound image, whereas adjacent portions of said model will appear bright in such an ultrasound image {paragraph 0051, ll. 11-13}; and, further comprising means for reversibly modifying {**"...removing the simulated patent skull suture fill material from one or more openings and replacing that material with the simulated fused skull suture fill material", paragraph 0057, ll. 14-17; or "...cover can simply be placed over the simulated patent skull suture fill material and the ultrasonic image would indicate that particular simulated skull suture was fused", paragraph 0067, ll. 4-13**} one or more selected simulated patent skull sutures to create one or more simulated fused skull sutures that can readily be detected in an ultrasound image, wherein each simulated fused skull suture will appear bright in the ultrasound image, like the portions of the model that are adjacent to the simulated

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

patent skull sutures {paragraph 0055, ll. 22-25}.

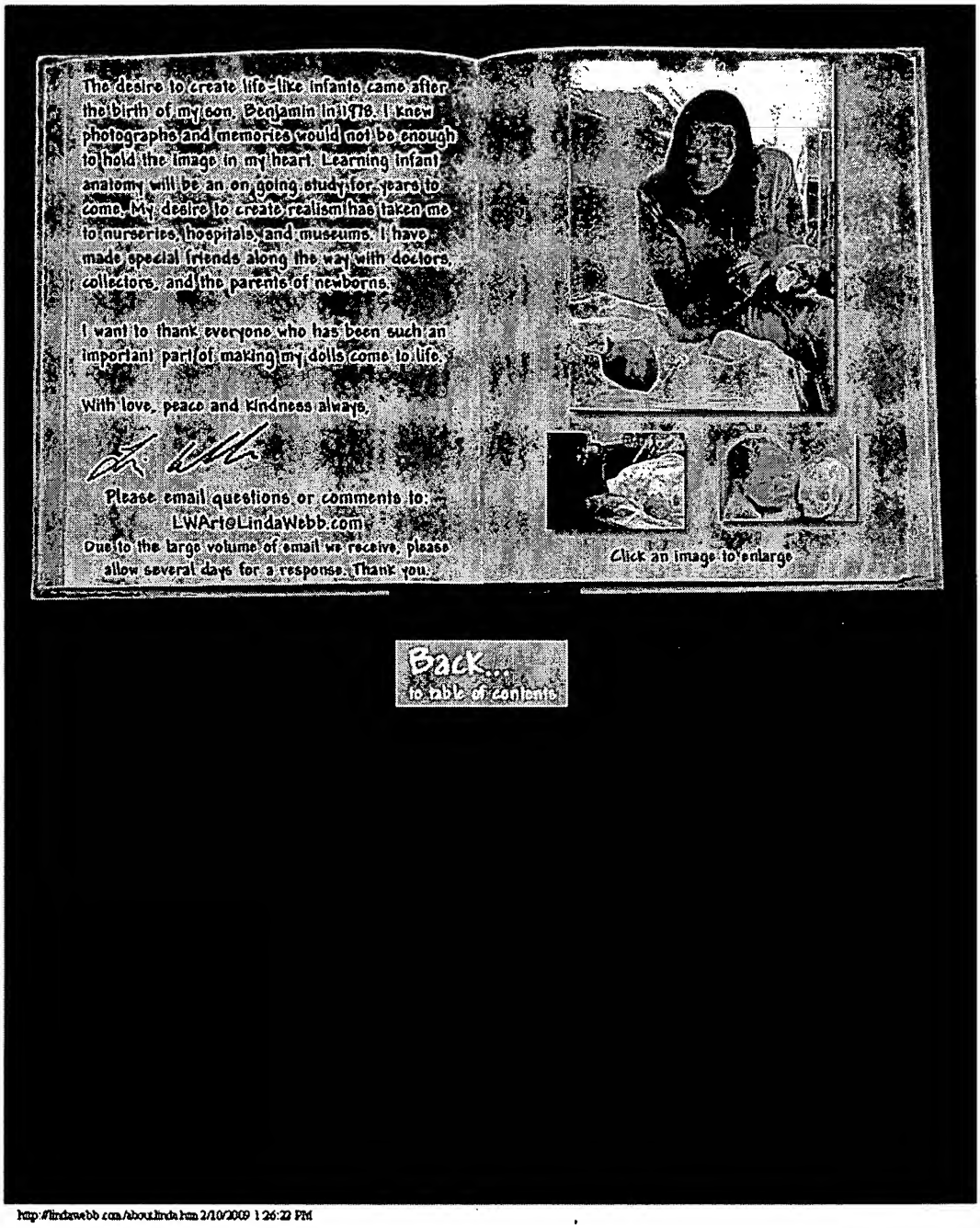
LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

EVIDENCE SECTION

TABLE OF CONTENTS

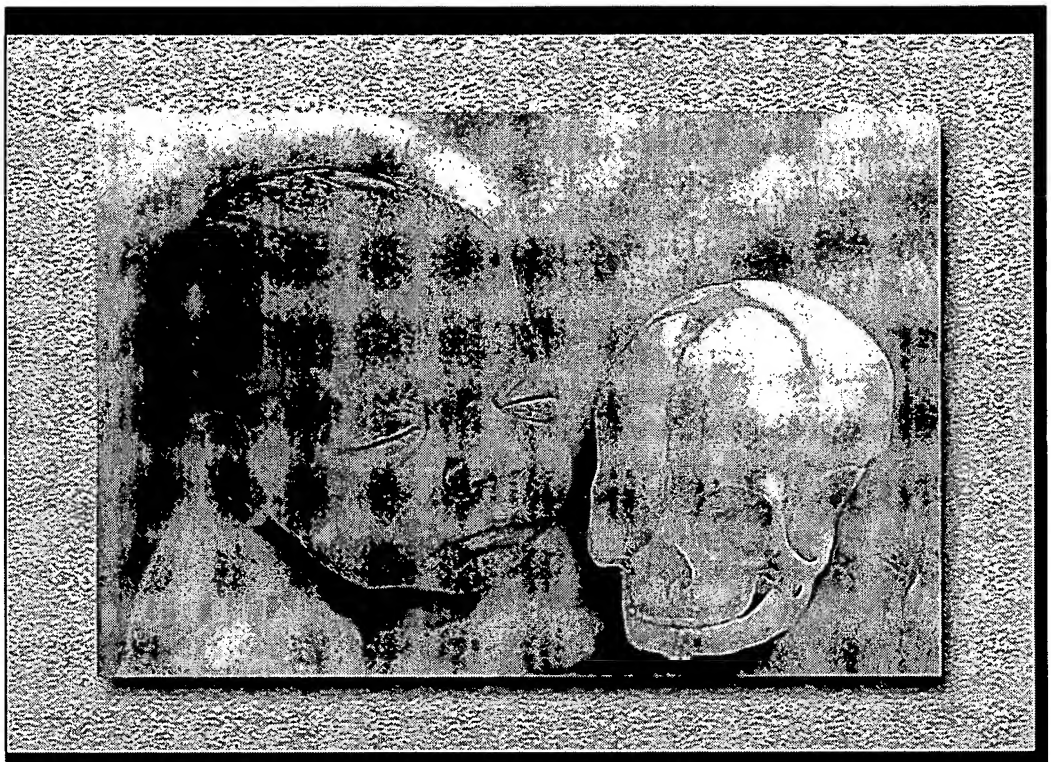
LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

http://lindawebb.com/aboutlinda.htm



LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

http://lindawebb.com/infant_skull.htm

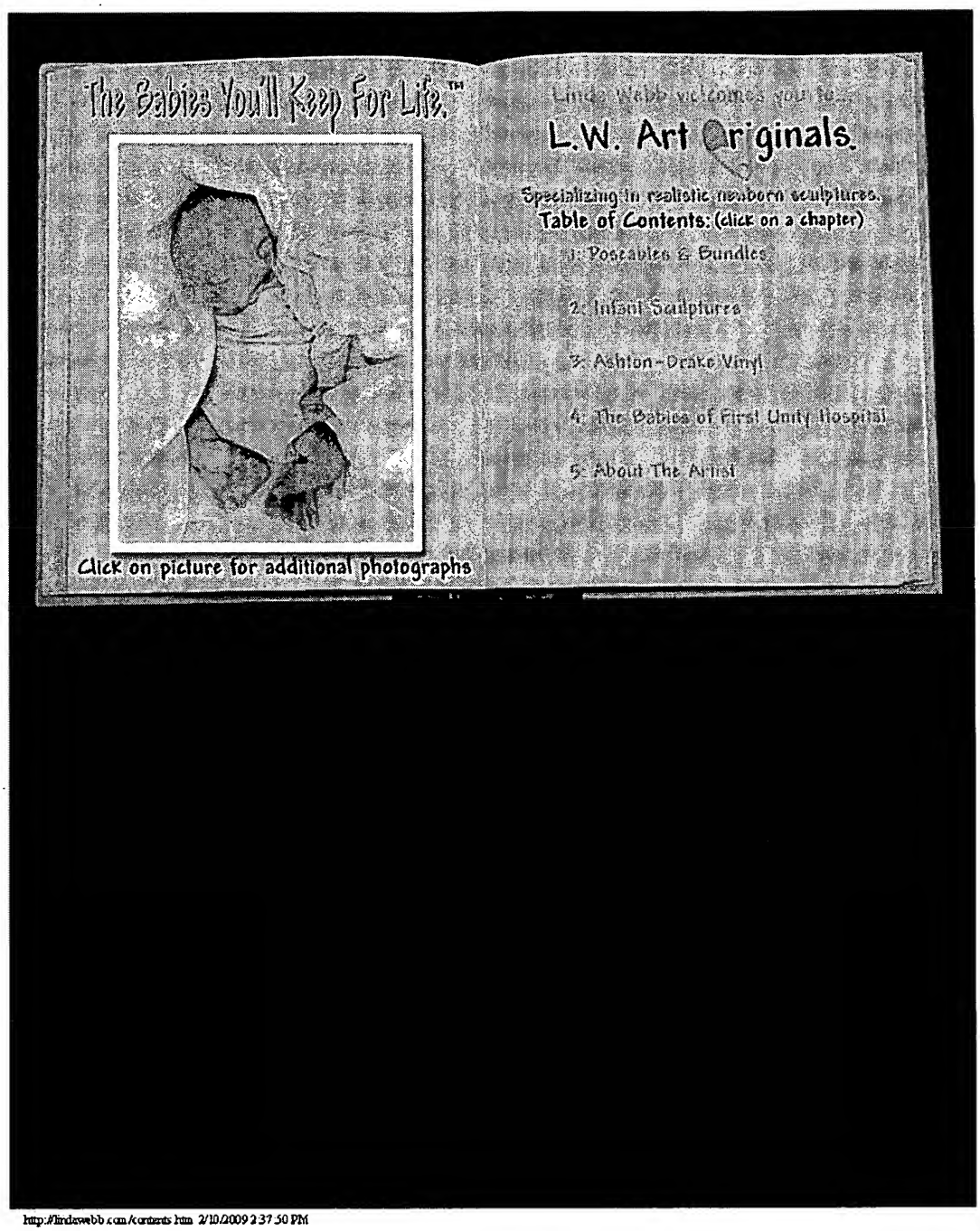


Infant skull model and sculpted head.

Linda uses this model to help her achieve the proper head shape of an infant

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

http://lindawebb.com/contents.htm



LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

RELATED CASES SECTION

There are no related cases to submit in this section.

LAW OFFICES OF RONALD M. ANDERSON
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816 Fax: (425) 646-6314

Respectfully submitted,

/sabrina k. macintyre/
Sabrina K. MacIntyre
Registration No. 56,912

Law Offices of Ronald M. Anderson
600 - 108th Avenue N.E., Suite 507
Bellevue, Washington 98004
Telephone: (425) 688-8816
Fax: (425) 646-6314
Email: sabrinam@lawofficesrma.com

SKM/RMA:elm